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Filing Date: August 22, 2003

REMARKS

Reconsideration is respectfully requested. Claims 1, 4, 9, 12, 15, 18, and 27-34 are pending. Claims 2, 3, 5-8, 10, 11, 13, 14, 16, 17, and 19-26 have been canceled. Claims 27-29 are withdrawn. Claims 18, 30, 31, 32, 33 and 34 have been amended. No new matter has been added due to the amendments. Amendment to and cancellation of the claims does not affect inventorship.

Applicants thank the Examiner for the allowance of claims 1, 4, 9 and 12. Claims 18 and 30-34 are rejected. Claim 15 is objected to.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Amendments

Claims 18, 30, 31, 32, 33 and 34 have been amended. Support is found in the specification, for example, in paragraphs [00125] and [00187].

Claim Objections

Claim 15

Claim 15 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependency form for failing to further limit the subject matter of the previous claim. The Examiner states that:

> The method of claim 9 is a crystallization method, whereas the method of claim 15 is directed to a method of structure determination of the protein using the product of the method of claim 9.

Applicants respectfully traverse the rejection for the reasons set forth below:

The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. § 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim. *See* M.P.E.P. § 608.01(n)

A dependent claim does not lack compliance with 35 U.S.C. § 112, fourth paragraph, simply because there is a question as to (1) the significance of the further limitation added by the dependent claim, or (2) whether the further limitation in fact changes the scope of the dependent claim from that of the claim from which it depends. The test for a proper dependent claim under the fourth paragraph of 35 U.S.C. § 112 is whether the dependent claim includes every limitation of the claim from which it depends. The test is not one of whether the claims differ in scope. *Id.*

The fact that the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper. Thus, if claim 1 recites a specific product, a claim for the method of making the product of claim 1 in a particular manner would be a proper dependent claim since it could not be infringed without infringing claim 1. **Similarly, if claim 1 recites a method of making a product, a claim for a product made by the method of claim 1 could be a proper dependent claim.** *Id.* (emphasis added).

In the instant case, as already noted by the Examiner, claim 9 recites the making of a product (protein crystal), and claim 15 is a claim directed to the use of the product, *i.e*, claim 15 is a claim **for the product** formed by the method of claim 9. The M.P.E.P. guidelines set forth above clearly state that a dependent claim such as the one set forth in claim 15 is proper. Although, claim 15 adds additional method steps, it includes all the steps of parent claim 9. Under the infringement test, claim 15 could not be conceivably infringed by anything that would not also infringe claim 9. Therefore, claim 15 is properly dependent from claim 9, and the Examiner is respectfully requested to withdraw the objection.

Claim 32

Claim 32 is objected to because of a typographical error. The typographical error has been corrected as requested by the Examiner. Therefore, the objection is rendered moot.

Claim Rejection Under 35 U.S.C. § 112

Written Description

Claims 18 and 30-34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that:

> The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

...

The phrase "non-crystalline" does not appear anywhere in the specification, and therefore, it is considered new matter.

Applicants respectfully traverse as follows:

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). **The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.** *See* M.P.E.P. § 2163.02 (emphasis added).

The Examiner appears to be taking the position that the term "non-crystalline" introduced into claims 18, 30, 31 and 32 by amendment constitutes "new matter" because the term does not appear anywhere in the specification. As the M.P.E.P clearly states, the claims need not use the exact same terms as used in the specification in order to satisfy the written description requirement. *See* M.P.E.P. § 2163.02. Additionally, the specification conveys the subject matter encompassed in the rejected claims. For example, claim 18 is directed to a non-crystalline protein consisting of SEQ ID NO:3, which represents amino acid residues 114-331 of Cathepsin S. SEQ ID NO:3 is described in Figure 1, which forms an integral of the application's specification. Additionally, the specification, see paragraphs [00187] to [00189] for example, teaches that in order to obtain a crystalline form of a protein, it is first necessary to express the protein in a soluble i.e, non-crystalline form following which, the soluble form of the protein is subjected to crystallization under appropriate conditions. It is unclear to Applicant what Examiner's issue really is. Since the specification clearly teaches the making of a soluble (non-crystalline) form of a protein, which in turn is crystallized to form a crystalline form of the protein, both crystalline and non-crystalline forms of the protein are taught. As such, the specification provides an

adequate description of both forms of the protein, and thus claims to both crystalline and non-crystalline forms are fully supported.

For the same reasons set forth above, the subject matter of claim 31 which is directed to an "isolated non-crystalline" protein consisting of SEQ ID NO:3 is supported by the specification, for example paragraphs [00187] to [00189], which teaches the expression and isolation/purification of a protein encoded by a portion of the Cathepsin S gene.

Similarly, claims 30 and 32 which are directed to a "non-crystalline" and an "isolated non-crystalline" protein consisting of residues 114-331 of SEQ ID NO:1 is supported by the specification, paragraphs [00187] to [00189] and Figure 1 (SEQ ID NO: 3 and SEQ ID NO:4). The referenced paragraphs teach the cloning of a portion of a gene encoding residues 1-331 of Cathepsin S, expression of the cloned protein, and purification/isolation of the expressed protein. Furthermore, SEQ ID NO:3 and SEQ ID NO: 4 provide descriptions of protein sequences that comprise residues 114-331, which can be prepared in non-crystalline form and isolated, based on the teachings of the specification at [00187] to [00189].

Regarding claims 33 and 34, the specification teaches SEQ ID NO:3 and SEQ ID NO: 4 that comprise residues 114-331, which can be crystallized based on the teachings of the specification at [00190] to [00192].

In sum, the specification provides sufficient description to convey to one of skill in the art that Applicants were in possession of the subject matter of claims 18, 30-34 at the time of filing of the instant application. As such, the rejection based on lack of written description is improper and should be withdrawn.

Enablement

Claims 18, 31, 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states:

> Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation.

Applicants respectfully traverse as follows:

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which

postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498,

With respect to claims 18 and 31 that are directed to a non-crystalline protein **consisting of** SEQ ID NO:3, Applicants have provided a detailed methodology of the process for isolating a non-crystalline form of SEQ ID NO:3 in paragraphs [00185] to [00187]. The scope of the claims is directed to a non-crystalline protein consisting of SEQ ID NO:3. Notwithstanding Applicant's disclosure, the methodologies of cloning and expression of proteins was very well known at the time the instant application was filed. Indeed, comparable to the scenario in *In re Wands*, there is considerable direction and guidance in the specification, and a high level of skill in the art at the time the application was filed, for one of ordinary skill to practice the claimed invention set forth in claims 18 and 31 (i.e., non-crystalline protein **consisting of** SEQ ID NO:3) without undue experimentation.

Regarding claims 33 and 34, contrary to the Examiner's assertions, Applicants have not claimed any crystal of the protein of SEQ ID NO:3 or a crystal containing residues 114-331 of SEQ ID NO:1, but rather have claimed crystals having specific space group and unit cell dimensions. With respect to claim 33 and 34, SEQ ID NO:3 and SEQ ID NO: 4 provide descriptions of protein sequences that comprise residues 114-331, while paragraphs [00185] to [00192] teach the methodology of crystallization of a protein. The disclosure, taken in view of the level of skill in the art, enables a skilled artisan to practice the claimed invention without undue experimentation. As such, the rejection based on lacking of enablement is improper and should be withdrawn.

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CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 442-1000.

Respectfully submitted,
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Dated: 8/7/07

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